



OCT 22 2004

**WARNING LETTER**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Tao of Herbs, Inc.  
3340 S. Wallace Street  
Chicago, IL 60616

To Whom It May Concern:

The Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.taofherbs.com> and has concluded that claims on this web site cause your products "Now Phase-2 500mg", "Now Chitosan with Chromium" and "Irwin Naturals Maximum Strength Phase 2 Carb Blocker" to be misbranded under the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and FDA's regulations through links on FDA's Internet home page: <http://www.fda.gov>.

Under section 403(r)(6) of the Act, dietary supplement labeling may include claims about the supplement's effect on the structure or function of the human body (structure/function claims), provided that certain requirements are met. [21 U.S.C. § 343(r)(6)(A).] One of these requirements is that the manufacturer of a dietary supplement bearing a "structure/function" claim must have substantiation that the claim is truthful and not misleading. [21 U.S.C. § 343(r)(6)(B).]

The labeling of Now Phase-2, Now Chitosan with Chromium, and Irwin Naturals Maximum Strength Phase 2 Carb Blocker bears structure/function claims, including the following:

**Now Phase-2:**

- "Now Phase-2, is an all-natural bean extract that inhibits alpha-amylase activity, thereby preventing the breakdown of dietary starches into glucose, allowing carbohydrate from starch to pass through the system unchanged."

**Now Chitosan w/ Chromium:**

- "Superior Fat Absorbing Action"
- "[Chitosan] binds to negatively charged fats during [sic] digestion and reduces their absorption."

- “Our product is formulated with Lipo San Ultra TM...designed to be a highly acid-soluble product with superior fat binding capability.”

**Maximum Strength Phase 2 Carb Blocker:**

- “Control Carb Craving”
- “[B]lock more carbs and lose more weight.”
- “Eat your favorite pasta, bread, cake or other treats without all the carbs turning to fat.”

Under “Ingredients” for Maximum Strength Phase 2 Carb Blocker::

- “Phase 2 White Kidney Bean Extract is the only material clinically proven to block starchy carbohydrates (e.g. bread, pasta, potatoes, rice) from turning into fat.” “In the stomach, it blocks the action of the enzyme alpha amylase from converting into sugar. Of course, this means that those sugars calories won’t get stored as fat.”
- “Magnolia Bark Extract...Reduces stress induced cravings.”
- “Chromium Picolinate...Normalizes...cravings.”

We have reviewed these claims and have concluded that they are not supported by competent and reliable scientific evidence. Because these claims lack substantiation, they are false or misleading, and cause your product to be misbranded within the meaning of sections 403(a)(1) and 403(r)(6)(B) of the Act. [21 U.S.C. § 343(a)(1), (r)(6)(B).] It is a violation of section 301(a) of the Act to introduce or deliver for introduction into interstate commerce any food, including a dietary supplement, that is misbranded. [21 U.S.C. § 331(a).] It is a violation of section 301(k) of the Act to commit any act with respect to a food if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being misbranded. [21 U.S.C. § 331(k).]

This letter is not an all-inclusive review of your web site and the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

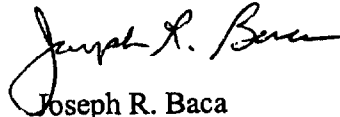
You should take prompt action to correct any violations, including the violations identified in this letter. Failure to do so may result in enforcement action, including seizure or injunction, without further notice.

If you have scientific evidence which you believe substantiates that your claims for Now Phase-2, Now Chitosan with Chromium, and Irwin Naturals Maximum Strength Phase 2 Carb Blocker are truthful and not misleading, please provide it to us within fifteen (15) working days of receipt of this letter. Alternatively, please advise this office, in writing and within fifteen working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to ensure that similar violations do not occur in the future. If corrective action cannot be completed with fifteen working days, state the reason for the delay and the time within which the corrections will be made.

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Your reply should be sent to the attention of Compliance Officer Quyen Tien at the above address.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Joseph R. Baca". The signature is fluid and cursive, with a large initial "J" and a long, sweeping underline.

Joseph R. Baca  
Director  
Office of Compliance  
Center for Food Safety and Applied Nutrition